



## Pharmaceutical Handling

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Specialized in Temperature Controlled Shipments for Pharmaceuticals

Pharma Process Forum

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## Pharmaceutical Handling

# The International Air Cargo Certification Program for Operators of Temperature Sensitive Air Shipments of Pharmaceutical Products



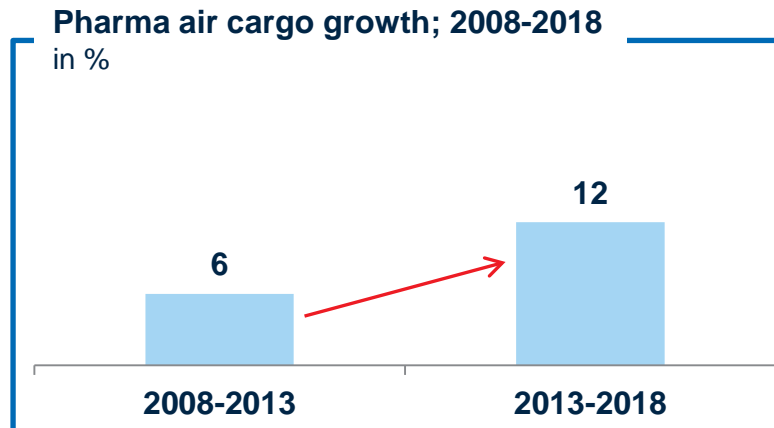
## Pharmaceutical Handling

What? · Why? · How? · Where?

**A concerted effort of the Air Cargo Industry to improve the level of competency, operational and technical preparedness for Temperature Sensitive Air Freight Shipments of Pharmaceutical Products.**

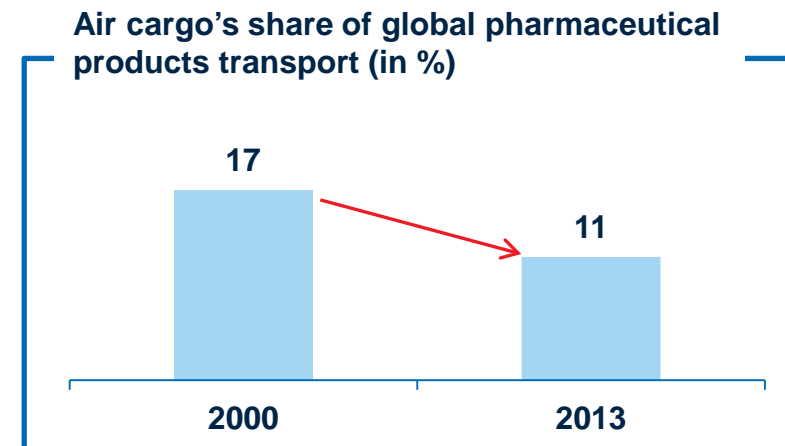
## The impact of mode shift on pharmaceutical logistics

The pharmaceutical industry has relied heavily on the airline industry for its speed and efficiency but air cargo's share of global pharmaceutical products transport has dropped



Over the past 10 years, air carriers, handlers and freight forwarders have responded with branded products and services to grab a share of this lucrative and niche market.

# HOWEVER



Source: Pharmaceutical Commerce

# Air Cargo Industry Concerns and Challenges

Heavily regulated industry with no global standards and certification for handling of pharmaceutical products

**Regulations for transporting pharmaceutical products vary around the world**

**WWW.COLDCHAINIQ.COM**

**A ONE PAGE GUIDE TO GLOBAL GDP GUIDELINES**

Good Distribution Practice (GDP) is the part of quality assurance which ensures that products are consistently stored, transported and handled under suitable condition as required by the marketing authorisation (MA) or product specification. There is no single global GDP standard. Cold Chain IQ has created this easy-to-assimilate summary of GDP requirements around the world, enabling you to navigate the landscape. You can keep it as a handy reference, share it around your colleagues or even stick it on your wall!

**KEY**  
Click for more information

**CANADA**  
#Guidelines for Temperature Control of Drug Products during Storage and Transportation (2011-2013)  
Health Canada

**UNITED STATES**  
#USP General Chapter <1079>- Good Storage and Shipping Practices  
#USP General Chapter <1080>- Good Distribution Practices- Supply Chain Integrity  
United States Pharmacopeia (USP)

**BRAZIL**  
#Opena public consultation on GDP and GDP Requirements on January 15. Deadline for comments March 12, 2013  
The National Health Surveillance Agency (Anvisa)

**ARGENTINA**  
#ANMAT Ley 26.462, Regulative de la cadena de frío de los medicamentos, N°10  
National Administration of Drugs, Foods and Medical Devices (ANMAT)

**UK**  
#Guidance in the Transportation of Medicinal Products, ambient and refrigerated Medicines and Healthcare products Regulatory Agency (MHRA)

**IRELAND**  
#MHRA - Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007 (SI 2011 of 2007)  
#MHRA Guide to Control and Manufacturing of Storage and Transportation Temperature Guidelines for Medical Products and Active Substances  
The Medicines Board (MB)

**EUROPEAN COMMISSION**  
#Detailed Commission guidelines on the distribution of medicinal products in the EU will enter into force September 8, 2013  
#Guidelines on Good Distribution Practice of Medicinal Products for Human Use  
#The principles of GDP are stated in Directive 92/25/EEC  
European Medicines Agency (EMA)

**DENMARK**  
#Executive Order No. 823 (GDAC 168449), Distribution of Medicinal Products, August 2012  
Danish Health and Medicines Agency

**INDIA**  
#Guidelines on Good Distribution Practices for Biological Products  
#DRAFT Guidelines on Good Distribution Practices for Pharmaceutical Products  
Central Drugs Standard Control Organization (CDSCO)

**SINGAPORE**  
#DRAFT Guidance notes on Good Distribution Practice  
Health Sciences Authority (HSA)

**AUSTRALIA**  
#Australian code of good wholesaling practice for therapeutic goods for human use  
Therapeutic Goods Administration (TGA)

**WORLDWIDE (WHO)**  
#Good Distribution Practices for pharmaceutical products TRS No. 957, Annex 5 (2010)  
#Model requirements for the storage and transport of time and temperature sensitive pharmaceutical products TRS No. 961 Annex 9 (2011)  
World Health Organization (WHO)

**IFPE Europe**  
#The IFPE - Europe Good Distribution Practices Audit Guidelines FOR PHARMACEUTICAL EXCIPIENTS 2011  
International Pharmaceutical Excipients Council (IPEC)

**China**  
#FDA Technical Report TR 52 (Aug 2011) Guidance for Good Distribution Practices (GDP) for the Pharmaceutical Supply Chain  
#FDA Technical Report TR 53 Guidance for Industry: Stability Testing to Support Distribution of New Drug Products  
#FDA Technical Report TR 58 Risk Management for Temperature-Controlled Distribution  
Pharmaceutical Drug Association (PDA)

**IATA**  
#Chapter 17 "Air Transport Logistics for Time and Temperature Sensitive Healthcare Products"  
IATA Perishable Cargo Regulations (PCR)

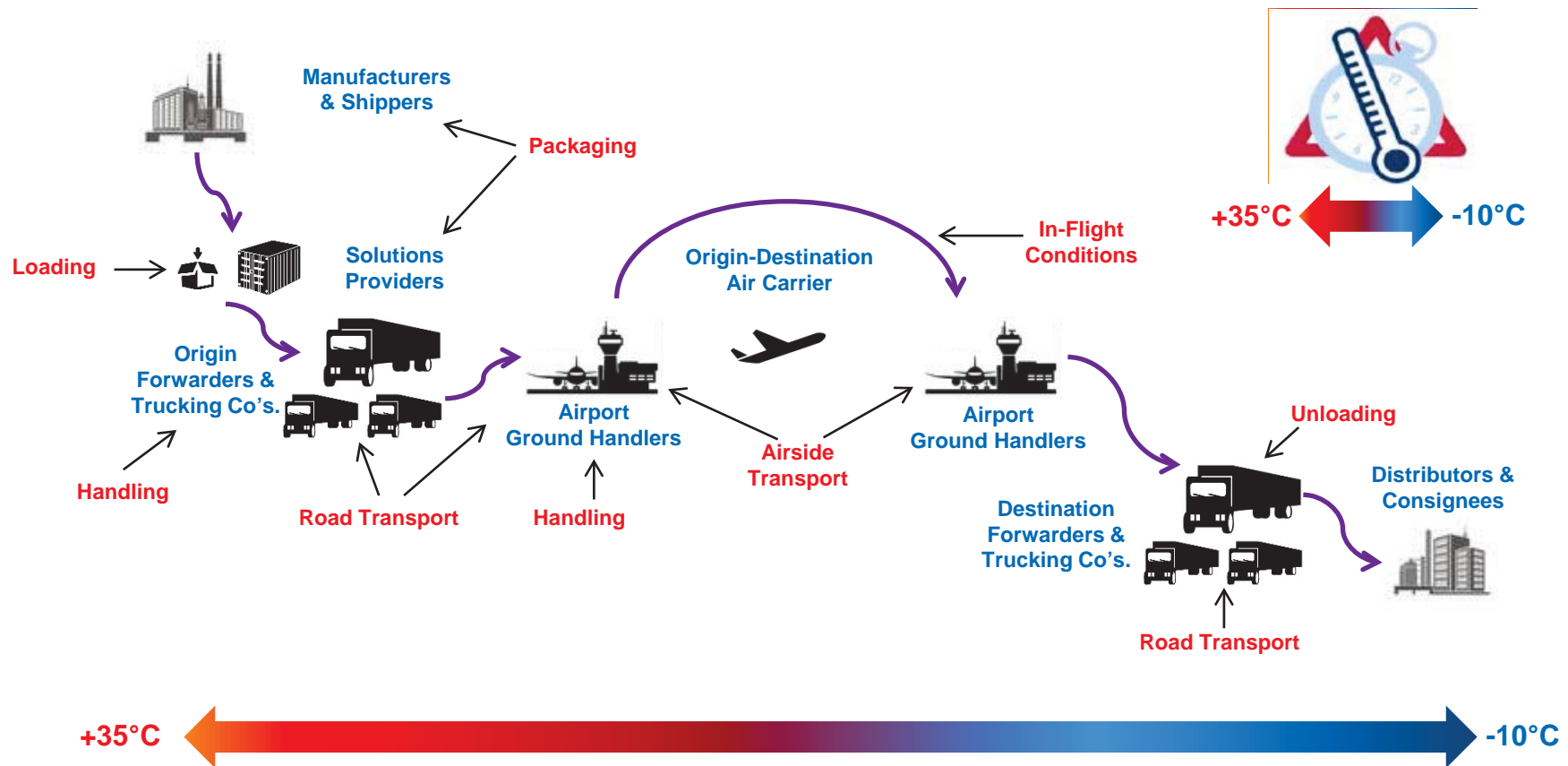
**CHINA**  
#Coming Soon: The newly revised Good Supply Practice for Pharmaceutical Products (GSP) will go into effect as of June 1, 2013  
State Food and Drug Administration, P.R. China (CFDA)

**CONNECT TO A COLD CHAIN IQ SOCIAL NETWORK**

- Increasing number of regulations around the world to implement and comply with.
- Increasing number of audits.
- Airlines, GHAs and forwarders subjected to multiple audits for handling, transportation and distribution (e.g. WHO Appendix 5, EU 92/25/EEC, IATA PCR Chapter 17 & TCR).
- No global certification for handling of pharmaceutical products.

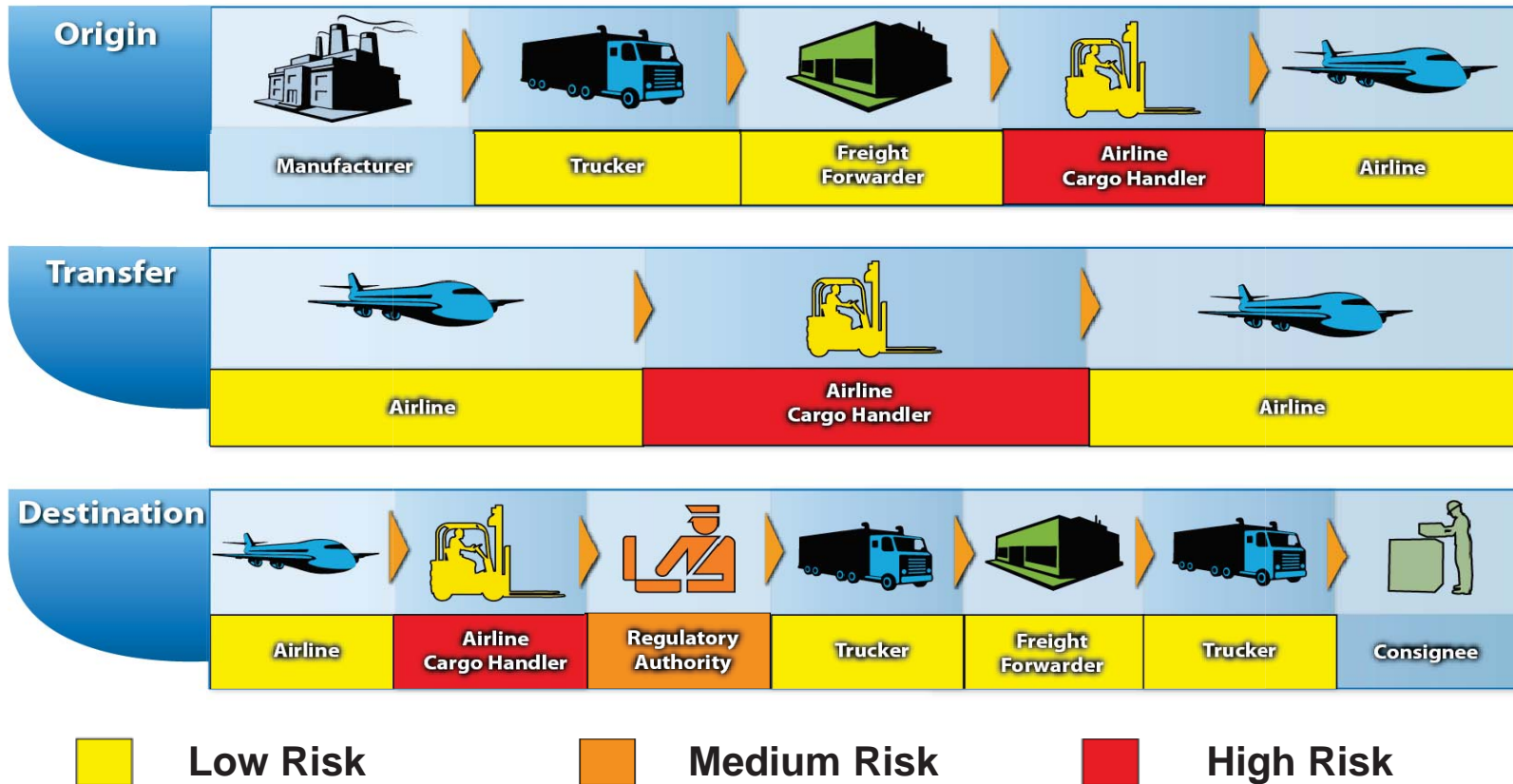
# Air Cargo Supply Chain Challenges

From origin to destination pharmaceutical products can be exposed to different climates



# Air Cargo Industry Concerns and Challenges

## Temperature Excursions – Where do they occur?



Source: Expeditors



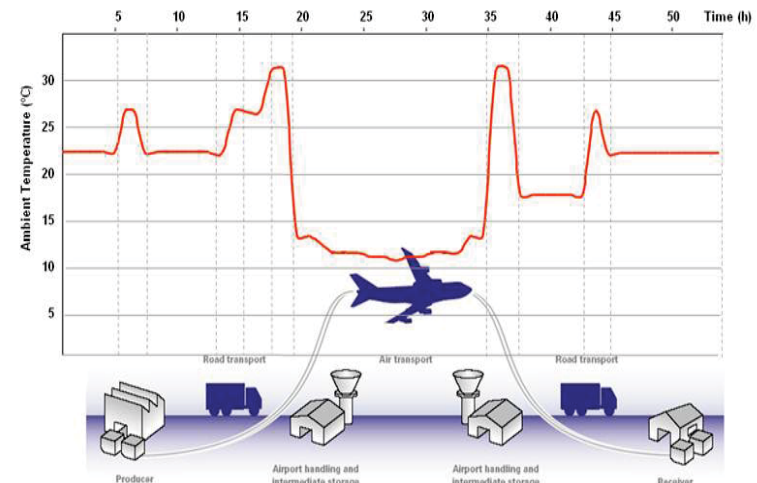
## Critical Issues Raised by the Shippers

Increasing shift in pharmaceuticals transported by sea due to air cargo challenges

- **More than 50% of all temperature excursions occur while the package is in the hands of airlines/airports**
- Temperature deviation denature the product, render it worthless and be harmful to the health of the patient
- Products can be lost, scrapped, returned leading to significant costs



- **Annual product losses between US\$2.5-12.5 billion due to various reasons including temperature excursions during transport and shipping.**



**Due to a lack of compliance, standardization, accountability and transparency across the air transport supply chain**

**The use of air-mode transportation is re-considered unless industry partners ensure quality services**

## Shippers Expectations in Cold Chain

Shippers need service providers that maintain product integrity and efficacy during transportation

- **Compliance, standardization, accountability and transparency** across the supply chain
- **Properly trained stakeholders** on regulations and standards
- **Adequately equipped facilities** throughout the supply chain
- **Global certification** for handling of pharmaceutical cargo
- **Common audit format** to minimize the disruptions and increase effectiveness
- Ability to **easily search and identify stakeholders that meet requirements**





## CEIV Pharma

To ensure the integrity of the product throughout the supply chain

# »» OBJECTIVES



**Prevent sanitary issues** caused by temperature excursions during transportation.

**Improve handling** of in compliance with existing regulations & standards.

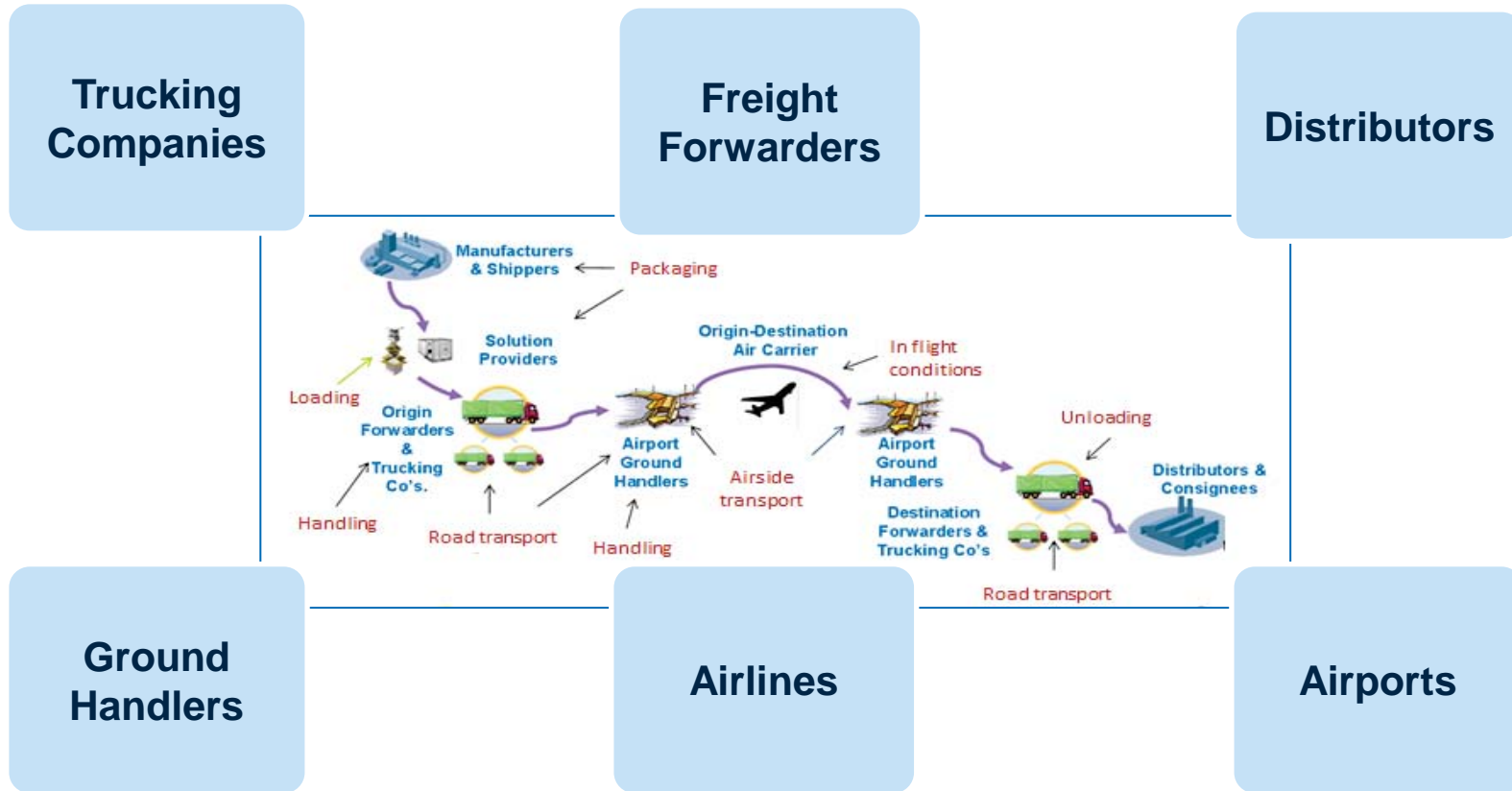
**Ensure product integrity**

**Elevate level staff competency** through efficient and robust training program.

**Create a global and consistent certification** that industry can rely on.

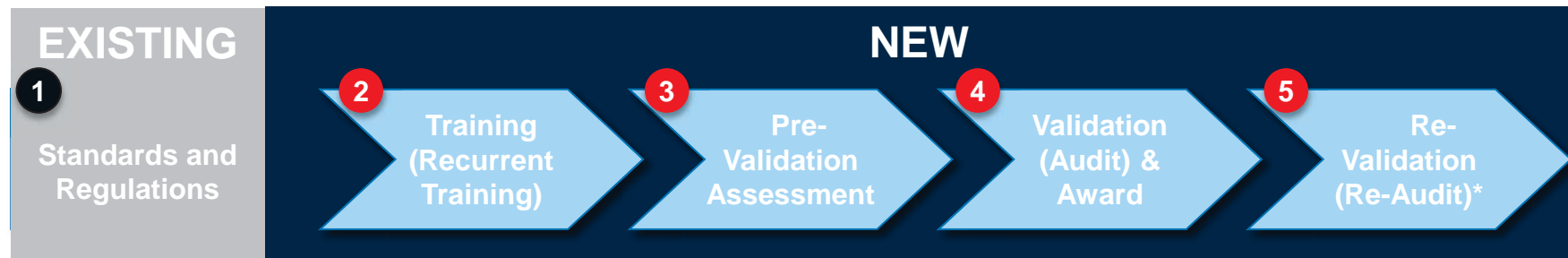
## CEIV Pharma targets

Who does CEIV Pharma target? The supply chain



## Center of Excellence for Independent Validators

### Approach of the CEIV



- **Advocate** for globally accepted standards and regulations
- **Train instructors** on behalf of the airlines, cargo and ground handlers
- **Manage** the pool of qualified instructors
- **Train the Independent Validators** to a common standard and validation methodology
- **Train operational staff**
- Run on-site **pre-audits** to prepare for validation
- **Conduct the validations**
- **Manage the database of Independent validators**
- **Manage the database of certified companies**





# Visibility for CEIV Pharma validated entities

Validated entities will become visible on IATA's website

## Search

IATA on-line repository of validated entities

Please enter your search criteria:

- Entity type: [ Select ]
- Entity name: [ Input field ]
- Validation type: [ Select ]
- Geographic area: [ Select ]
- Country: [ Select ]
- City: [ Input field ]
- IATA airport code: [ Input field ]
- Validator last name: [ Input field ]

Submit

## Results

Type	Name	City	Country	IATA Airport Code	End of validity date of audit		
					EU 185/2010-RA3*	EU 185/2010-KC2*	IATA CEIV Pharma
	Dog screener PLG	MusterCity2	Thailand	SDF	03-Sep-18		
	Easy forwarding	MusterCity3	India	ABC	04-Jan-19		03-Nov-18
	AirlineX	MusterCity5	The Netherlands	AMS			05-Aug-18
	AirlineX	MusterCity2	Thailand	BKK			05-Sep-18
	GHA_ABC	MusterCity	Columbia	ABC	15-Jul-19		
	GHA_ABC	MusterCity	Columbia	RTY	04-Jun-19		
	GHA_ABC	MusterCity	Columbia	CBA	04-Jun-19		05-May-18
	Shipping unlimited	MusterCity4	Vietnam	SDG	08-Apr-19		24-Jun-17

## Details on a validation

Detailed information regarding CEIV Pharma Certification

Easy Forwarding

Entity information:  
Legal name: FF POI      Address: Mumbai road 33  
Doing business as: Easy forwarding      Zip code: 54321  
Type: Freight forwarder      City: MusterCity5  
Country: India

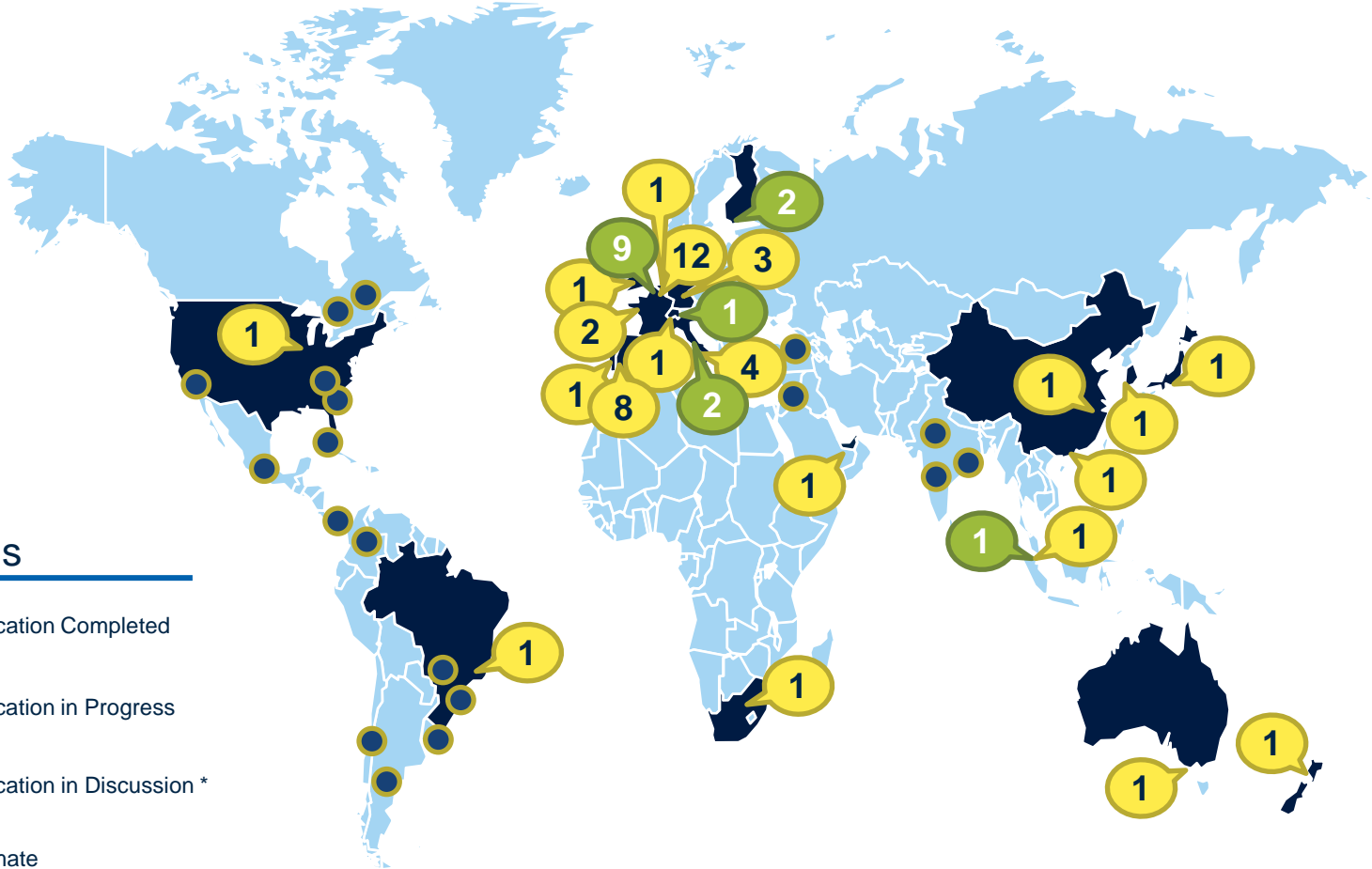
Validation information:  
Type: EU 185/2010-RA3  
IATA Airport Code: ABC  
Valid through: 04-Jun-19  
EU independent validator name: Musterfirstname Musterlastname

Disclaimer: The information displayed on this page is as provided by the Independent Validator mentioned above. IATA provides no guarantee on the accuracy of this data.

Note: Please report any inaccurate content to [ceiv@iata.org](mailto:ceiv@iata.org)

# CEIV Pharma

## Certified Pharmaceutical Trade Lanes Development



### Locations

- 15 Certification Completed
- 44 Certification in Progress
- 97 Certification in Discussion \*

\* Estimate

# THANK YOU

For further information, contact:

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Pharmaceuticals

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